

Connery, Shannon

From: Boyd, Andrew
Sent: Friday, June 05, 2015 9:51 AM
To: Connery, Shannon
Subject: FW: UAO for FMC IRODA /FMC FOIA

From: Jill Grant [mailto:jgrant@jillgrantlaw.com]
Sent: Wednesday, May 06, 2015 7:30 AM
To: Boyd, Andrew
Cc: Bill Bacon (bbacon@[REDACTED]); Kelly Wright (kwright@[REDACTED]); susanh@[REDACTED] Virginia Monsisco (vmonsisco@[REDACTED])
Subject: UAO for FMC IRODA

Good morning Andy,

Do you know whether FMC has fulfilled its obligations to provide a performance guarantee pursuant to Paragraphs 67 & 69 of the UAO for the FMC IRODA? Could you let me know, and also let me know which of the methods listed in Paragraph 67 FMC used to provide the guarantee?

Thanks,

Jill

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Connery, Shannon

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Sent: Friday, June 05, 2015 9:51 AM
To: Connery, Shannon
Subject: FW: UAO for FMC IRODA / FMC FOIA

From: Boyd, Andrew
Sent: Wednesday, May 06, 2015 7:36 AM
To: Williams, Jonathan
Cc: Sheldrake, Beth
Subject: FW: UAO for FMC IRODA

See message below from Jill Grant. Please let me know how FMC has satisfied these obligations and I'll pass the info on to Jill Grant.

Thanks

Andy

Andrew Boyd
U.S. EPA, Region 10
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FOR USE OF RECIPIENTS NAMED ABOVE

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([vmonsisco@\[REDACTED\]](mailto:vmonsisco@[REDACTED]))
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Connery, Shannon

From: Boyd, Andrew
Sent: Friday, June 05, 2015 9:52 AM
To: Connery, Shannon
Subject: FW: SEP 14 -- Meeting Notes / FMC FOIA
Attachments: SEP 14 SDP Conf Call Notes 4 29 2015.docx

From: Lizanne Davis [mailto:Lizanne.Davis@fmc.com]
Sent: Tuesday, May 12, 2015 1:11 PM
To: Robert Forbes; David Heineck; Rosalind Schoof; Bill Bacon; Danny Stone [REDACTED]; tamartin@[REDACTED] susanh@[REDACTED] Boyd, Andrew; Frank; 'Tom Gesell'; Gandy, Jay; porris@uic.edu; 'Ray Kary'; 'Jerrold Leikin'
Subject: SEP 14 -- Meeting Notes

Dear All,
Attached are draft notes of our discussion. Please provide edits and I will finalize. I have yet to finalize a date for the SDP discussion with Exponent – David Hoel is out of the country and Dominik Alexander is in depositions on the dates we had identified (May 19 or 20 at 3:00 EDT). Will advise.
Best,
Liz

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SEP 14 – SMT/SDP CONFERENCE CALL

APRIL 29, 2015

3:00 – 4:03

Bob Forbes

Dave Heineck

Roz Schoof

Susan Hanson

Talia Martin

Andy Boyd

Frank Gilliland

Jay Gandy

Tom Gesell

Peter Orris

Jerry Leiken

Ray Kary

Liz Davis: Purpose of the call is to hear the SDP's opinions on whether the report carried out the work specified in the study design and the Phase I report which the SDP approved. The SMT would also like your thoughts on how to communicate the results to Reservation residents.

Ray Kary: Are any of the authors of the report on the call?

Liz Davis: No that opportunity was offered to the SDP prior to this call but no one took up the opportunity.

Peter Orris: You're going to have questions that only the authors can answer.

Liz Davis: Are you saying you want a call with the authors?

Ray Kary: Let's talk about our concerns and then a talk with authors. Let's go page by page.

Peter Orris: Agree.

Liz Davis: let's have the SDP review today issues they have with the draft report, then we will schedule a conference call for the SDP with Exponent.

Jerry Leiken: as this discussion moves forward, more questions will likely pop up.

Peter Orris: I would want to talk to Exponent to understand what I don't see in this report – I'd like to know whether it exists or whether they determined it just wasn't important.

Frank Gilliland: I'd like to understand the purpose of this document, -- is it meant to address community concerns about health effects from FMC's operations or is it meant to meet the requirements of consent decree.

Ray Kary: should both be the same, but not sure it meets requirements of CD. I have a problem with some of the approach on gathering data, especially from the Tribes – there is absolutely no response from the tribes but don't know that it can be fixed.

Peter Orris: What is the organization of this report.

Roz Schoof: Let's answer the first question raised. The work plan established by the SDP and approved by EPA was to meet the objectives of CD. This report is execution of that effort.

Dave Heineck: Correct, we have an EPA approved study design work plan, phase I and II as required with SDP input and EPA approval. Meeting the consent decree requirements means having a study that lines up with the design. The question is whether the study was done as specified and outlined in the work plans. Did the study do the work we called for in phase I and II. That really is equivalent to CD compliance. Focus should be on lining up the study with the work plan to determine whether it matches and addresses the issues which the work plan called for.

Peter Orris: I agree.

Frank Gilliland: Part of this is communicating to community the purpose of the study. I think that if you read the report from a community perspective, it is not directed toward addressing community concerns but more to addressing a scope of work. I wouldn't want to be the person standing up and presenting it to the community.

Roz Schoof: That's part of SMT's job to design communication materials that are aimed at the community.

Peter Orris: Let's go over the report and raise the questions that each of us have so that authors have warning before we get on a call with them.

Liz Davis: Agree and in a previous call, the SMT agreed at the onset that the report needs to be put in context in terms of its origins.

Dave Heineck: I am working on an explanation of the basis for the study to be added to the report and SMT is best situated to do this work.

Peter Orris: Will it include a description of plant operations, and the concerns expressed by the community?

Dave Heineck: No, the CD required the study be done.

Peter Orris: There ought to be something in here, not long, but a historical reference to plant operations, just as background so that it's one piece that you could read so you don't have to go find it elsewhere.

Dave Heineck: Yes, good idea, perhaps as an appendix, preference as appendix or exhibit but yes, background in one document makes sense to me.

Bob Forbes: There are probably pieces like that already written in other reports that we can draw from.

Peter Orris: Might make sense to use the ATSDR report directly given that it is a government report and an already accepted/approved document.

Ray Kary: A two page introduction that goes through that would make it easier.

Peter Orris: That leads into the CD and what happened derivative.

Ray Kary: And some detail about the CD.

Peter Orris: Don't want to leave out ShoBan Tribes.

Ray Kary: Yes that would all be part of it.

Dave Heineck: Don't want to dilute that this is an Exponent report, but perhaps a separate document that the SMT would develop, put into an appendix or memorandum.

Liz Davis: Let's start with the Executive Summary.

Peter Orris: Problem with that is the Executive Summary is an abstract of the report and a reflection of the content of report itself. So, let's start at background.

Ray Kary: The study did not collect additional environmental sampling data – certainly some information is missing and would have been easy to get and I have an objection to that.

Liz Davis: Are there any other comments -- then proceed to General Overview.

Peter Orris/Jerry Leiken: No problems.

Frank Gilliland: page 3, provides a description that Tribal events were severely under attended, disinterest in research efforts – lack of interest more apparent by sparse response. This is reflective of the entire tone of the report and is culturally insensitive. Any researcher who works in these communities knows there's a severe lack of trust, especially toward outside researchers coming into their community in general. It seems this is more a lack of success by the research team than attributing disinterest to the community. Really need to change that general tone and approach to the tribe and tribal response to their effort.

Ray Kary: Totally agree. Tribe simply doesn't trust the researchers and the team couldn't overcome that.

Jerry Leiken: Agree – second to last sentence in first paragraph – not really needed or germane to entire effort.

Peter Orris: Needs to be stated in an objective way by not indicating where the fault lies or the study researchers were not able to secure the kind of response necessary for this study to be effective. Just needs to be stated objectively. Don't want them to beat themselves over the head either, but people need to be able to see the study for what it is.

Peter Orris: This discussion also is not meant to be exhaustive, but should serve to just to warn them about what we're going to say to them when we get on the phone with them.

Peter Orris: On page 5 – this is a cookie cutter description. Would have like to have seen on page 5 a map that shows census tracts, counties, and comparative counties. Only map I saw was of Reservation and plant. Should have more expansive visualization.

Ray Kary: Agree, should have full page map.

Jay Gandy: Agree, only map is on page 21, deep into the report and very small. Had to go to Google Earth to get a better perspective.

Tom Gesell: Agree, census tracts would be helpful.

Peter Orris: CHSD – what is it?

Jay Gandy: I looked too and couldn't find it.

Roz Schoof: page 14 Contract Health Service Delivery areas.

Peter Orris: Would be helpful to put up front.

Frank Gilliland: Missing description denominators – how rates were determined. Critical and not easy to define denominators that go with these ascertainties of death or cancers for a lot of different reasons. No description and it is a critical missing item.

Peter Orris: Are we now into cancer/total mortality?

Liz Davis: Let's keep with the approach and move to Methodological and Analytical.

Tom Gesell: Made some editorial issues and marked them up. Not worth time to discuss each one but would like to transmit to authors for their consideration. (*Tom has since provided this document which will be distributed*)

Peter Orris: I have some global stuff about methodology and missing discussion in the report. I assume this entire methodology of comparing rates in counties and places assumes a uniform population; age distribution which I have no problem with. But some statement is needed as to why it's assumed and basis for assumption. Otherwise some discussion of age related cancers have to come into it. No isolation of childhood leukemia for one, because of limited latent period and sensitivity of children to those exposures. Some age related cancer stuff that has previously been identified as sensitive or why it is not included. Overall comparison may be all we can do but not state of the art.

Tom Gesell: There is some age adjustment.

Jerry Leiken: There is data missing from tables also.

Jay Gandy: I had similar comment on center paragraph on page 8 – it would be helpful to have this more flushed out.

Peter Orris: The result calls into question these methodologies and results -- concerned about the finding of rates to be half of what you'd expect in the State as a whole – not just target area and counties as well. When you find rates that are half of State as a whole, it calls into question, most specifically case identification; where people go for care/where they are diagnosed/what was used to identify where they live, or overall migration patterns that are not discussed at all. For example, if everyone leaves when they're 25, it gives you a different approach. Why did the study find the rates on the Reservation where half of the State? Is it lifestyle? Need some explanation of this otherwise it calls into question the methodology.

Jay Gandy: Goes to bigger issue – there is no overall discussion of the results or the strengths and weaknesses of the results.

Ray Kary: Now I'm going to come out of left field, but normal operation on the Reservation is for people go to the medicine man and you might poo poo it, but that is part of their culture and there is no data on that. Just mentioning that in report and saying it could not be dealt with. Particularly true on this Reservation, there's a book on it which I bought while at Fort Hall.

Peter Orris: I'll circulate around a general comment – biostatisticians can't do epidemiologic studies – not a question of statistics. The study does not give adequate information that the researchers understood the community they were studying. None of these things necessarily make the study invalid, but it needs more there so that it can be understood, in terms of its limitations and validity.

Liz Davis: Let's move to Cancer, Mortality and Sentinel Events.

Peter Orris: I would like to list a couple that they did not find.

Jerry Leiken: Want to discuss the section on Sentinel Events (SE), I find it totally inadequate -- what SE did they look at overall, I'm looking at the study abstract of 2009, they do mention phossy jay, but not the others identified, feasibility on part 1 and not other 10 parts. Just totally inadequate.

Peter Orris: I have a question -- did they think that this was covered by the mortality review or that they could not get to medical records. Limitations are not clear.

Frank Gilliland: In looking at the methods for cancer and mortality, they suppressed any which were less than 5, when with SE, just 1 would be important.

Jerry Leiken: They discuss rheumatoid arthritis (RA) and lupus, but these are not sentinel events. What was that for?

Peter Orris: The definition relates to rates. You could extend SE to that but, in fact, a SE of 1 means something.

Jerry Leiken: Exactly, that's how it was defined in the original protocol.

Jerry Leiken: The circulatory system is the only one to rise as opposed to fall in remainder of Idaho.

Peter Orris: There are digestive elevations – don't know what consistency means and no comment on it.

Jerry Leiken: Table 10 is somewhat significant, needs statistical analysis, more of an investigation.

Would like to see 5th column, comparative. Circulatory and digestive.

Peter Orris: I think they're only trying to give us trends. I think the one you're talking about is the next one – 11 and 12 comparison with other studies of similar ethnic groups.

Jerry Leiken: Table 10 needs explanation -- MI/heart disease and stroke.

Peter Orris: Table 10 was supposed to tell whether or not any were increasing in time/areas or decreasing when the plant shut down. And how that related in the change in the State as a whole.

Ray Kary: Can't make that assumption with that data.

Jerry Leiken: Tables 10, 11, 12 need more explanation and statistical analysis.

Peter Orris: There is an age specific comparison but not terribly relevant to situation. But I would like to see something like that for the cancers. Why are the mortality rates so much higher for Freemont County and lower for Fort Hall. Page 25. The implication is that for the Fort Hall population is much healthier and maybe so but some discussion here would be helpful.

Ray Kary: There is nothing to do with when the plant closed.

Tom Gesell: I'm not understanding what they meant by age specific.

Ray Kary: Agree, could be a better discussion.

Tom Gesell: Maybe it was a birth year.

Frank Gilliland: The table needs to be corrected and explained.

Jerry Leiken: Should there be confidence intervals with this?

Frank Gilliland: Yes that would be good because then you would have some idea of uncertainty of the estimates and how they compare.

Tom Gesell: I thought the numbers were based on deaths.

Frank Gilliland: Yes but confidence levels will give a signal of whether it's higher or lower.

Peter Orris: Just want someone to tell me why these rates are accurate.

Liz Davis: Let's move to Asthma, page 27

Peter Orris: There is a long discussion about how they couldn't do the study, and I can understand that based on lack of cooperation. Not ascribing whose problem that was.

Frank Gilliland: Why couldn't they get access to Indian Health Service (IHS) records?

Peter Orris: Did they have difficulty getting permission from an IRB?

Ray Kary: The IHS should not have been a problem.

Talia Martin: They did have access to IHS but it's both tribal and federal, so they had access to the fed's but not the tribal side. Plenty of access but not in a timely manner. I would like to understand this better.

Jerry Leiken: The report should talk about IRB process as more than a footnote.

Peter Orris: We had discussed at some point that if they had a local practitioner, there would be some information even if it wasn't quantifiable both for SE and asthma and there is just no description of local interaction. Then again, it may not have made it to final protocol that SDP let out.

Jerry Leiken: Agree and in study abstract.

Ray Kary: I remember discussing that. I thought they were going to interact with local physicians.

Jerry Leiken: Yes. We even identified dentists, veterinarians. It was in the March 2009 study abstract.

Peter Orris: That covers it for me. Don't know what the appendix gives us, except the survey that didn't work.

Ray Kary: Yes, it's hard to read. Failed miserably on that survey.

Peter Orris: I think it's a good first draft, now let's go to work on the specifics.

Tom Gesell: I have a SE comment – there was a comment by Dominik on RA/lupus, his statement was that these outcomes were high but don't have reference

Peter Orris: It is high among Native Americans, but not sure about this group necessarily.

Frank Gilliland: I'd like to state that in summary for asthma section – they keep making point of no registry but the diagnosis for asthma is variable and needs individual level info from community health/people themselves. Don't think that's germane to this – weren't able to obtain cooperation from individual tribal members to participate in data collection or IHS/clinical facilities in area and that the issues around asthma are not borne out by literature. There is lots of information that asthma is not based on individual self reports or symptoms. The whole summary is off base that they weren't able to obtain information for the period.

Liz Davis: Do you want to return to the Executive Summary for comment?

Jerry Leiken: There is no discussion of table 1-0, the reference to SE is lengthier in Executive Summary than in body of paper.

Peter Orris: SE is a missing part of study – not finished.

Ray Kary: My overall impression is that this needs another shot and rewrite.

Frank Gilliland: On the issue of geocoding and how residences were assigned – most people have PO boxes and not residential addresses – how was that handled and how does that affect assignment to census tracts and to counties?

Jay Gandy: That underscores overarching critique – the report needs descriptions of methodology because detail is not provided on how they got the material to get to the results.

Peter Orris: SMT should consider withholding final payment until this is revised.

Andy Boyd: The methodology for the study was established in the work plan.

Peter Orris: Yes, the 10,000 foot about what could be done.

Andy Boyd: And the methodology left a lot to the discretion of the researchers.

Peter Orris: It was intended to point them to the mountain and then it was their job to decide how to get there.

Andy Boyd: Did the work plan not have sufficient direction to direct methodology. It was a two phased work plan -- am I hearing that the work plan didn't have sufficient detail to address methodology questions?

Peter Orris: We don't know, because we don't have an adequate description in this draft report.

Jerry Leiken: There must be some comparative statistical data that they didn't include in this draft. Some provision of 2013 report is not incorporated into 2015 report.

Jerry Leiken: Not sure they went to all known data bases.

Peter Orris: You didn't hire technicians -- you hired epidemiologists so this is the kind of information that they're supposed to know how to do and present. Maybe they had a change in personnel and didn't know what they're doing.

Bob Forbes: Have to depart.

Liz Davis: Asked for dates for call with Exponent and group agreed to either May 18, 19 at 3:00 EDT. These notes will be circulated to SDP/SMT for review/edit and provided Exponent prior to conference call.

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